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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,140	11/05/2001	Lyn Hughes	A01317	1934

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EXAMINER	
LUDLOW, JAN M	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,140	HUGHES, LYN	
	Examiner	Art Unit	
	Jan M. Ludlow	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/1/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 19-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19, part c is not described in the specification as filed because only small particles are removed via the dip leg, not "any undissolved portion". In claim 19, part c), "passing the release medium through the cells such that..." is not supported because passing the medium through the filtration and UV cells does not result in the claimed function—it is passing the medium through the filtration cell and the dip-tube that provides this function. In claim 19, part e), there is no support for controlling the temperature of the UV cell. While there are some references to temperature control of "the cells" it is not in the context of describing the filtration and UV cells, and therefore appears to be either a typographical error, or reference to plural filtration cells. See, e.g., page 3, lines 70-85. In contrast, when the filtration cell and UV cell are referred to, the UV cell is not temperature-controlled (e.g., page 4, line 121- page 6, line 169). Claim 20 is not supported because it is conditions in the filtration cell (which simulates the mouth) that are relevant physiologically, not the UV cell.

It is strongly suggested that applicant's registered representative more carefully review the specification as filed before preparing any amendment.

2. Claims 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19, part c) does not make sense because "passing the release medium through the cells such that..." does not result in the claimed function because passing the medium through the filtration and UV cells does not result in the claimed function—it is passing the medium through the filtration cell and the dip-tube that provides this function. Claim 19, part d) does not make sense—what does removing samples from the UV cell have to do with the samples not containing any undissolved material? In the invention as disclosed, samples having the undissolved particles removed by the filter are removed form the filtration cell and passed through the UV cell.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Compton et al in view of Olson (3,620,675).

Compton teaches a method for sampling a dissolution vessel having a stirrer and temperature control (col. 2, lines 41-48). A sample is withdrawn via needle 20 and particles are removed from the vessel and trapped in filter 32. Particle-free sample passes through the filter and may be passed to a flow-through analyzer, such as a flow injection analyzer or chromatographic system (col. 4, line 6-12).

Compton fails to explicitly teach passing release medium through the cell or adding a test sample or a UV flow cell.

Olson teaches a dissolution test with a UV flow cell analyzer 23.

It would have been obvious to provide a UV flow cell in the flow through analyzer of Compton in order to analyze dissolution samples as taught by Olson. It would have been obvious to provide release medium and sample in the dissolution vessel in order to test the sample for dissolution as disclosed. Note that the medium "passes through" because it is supplied and withdrawn. With respect to claim 25, it would have been obvious to optimize the size of the needle to remove desired volumes at desired rates. Note further that the instant claims do not preclude back-flushing the particles into the dissolution cell or otherwise distinguish over Compton.

6. Applicant's arguments filed March 17, 2006 have been fully considered but they are not persuasive.

7. Applicant argues that "any undissolved portion" being removed is supported because "undissolved components" exemplified by small particles are disclosed as

removed. This is not persuasive because it is clear from the disclosure that, e.g., particles larger than the inner diameter of the dip tube, or otherwise not meeting the hydrodynamic criteria specified for removing particles, will not be removed; thus "any undissolved portion" is not supported.

8. Applicant's definition of "small particles" as found in the specification is accepted.

9. The obviousness-type double patenting rejection is overcome by the amendment, e.g., by requiring a filtration cell not claimed in Patent No. 6,799,123.

10. Applicant argues that Compton does not disclose a rapid test, but the instant claims are not so limited.

11. In response to applicant's arguments, the recitation "buccal" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml

May 29, 2006